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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,708	09/18/2003	Steven T. Brentano	GP107-03.DV1	6892
21365 7590 01/18/2007 GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE Mail Stop #1 / Patent Dept. SAN DIEGO, CA 92121			EXAMINER SWITZER, JULIET CAROLINE	
			ART UNIT	PAPER NUMBER
			1634	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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patentdept@gen-probe.com  
kelleec@gen-probe.com

**Office Action Summary**

Application No.

10/665,708

Applicant(s)

BRENTANO ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 10/30/06. Claims 1, 8-20 have been amended. Claims 1-20 are pending. Claims 1-12 are withdrawn from prosecution. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite

#### *Claim Rejections - 35 USC § 102*

4. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by GenBank X53896, GI: 44201, published 04 September 1991.

For this claim the word "kit" is being broadly interpreted so as to include the teaching of the recited reagents or molecules since a "kit." The word "kit" does not provide any structural requirement, and is being treated as a recitation of intended use. Further, because claim the

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recites that the kit "contains" one or more oligonucleotides selected from the group consisting of SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, and SEQ ID NO: 24, the claim is drawn using open claim language. Since there is not transitional language which directly modifies the recitation of the SEQ ID NO, the only transitional requirement is that the kit "contain" the oligonucleotides. Thus, the claim is drawn using open claim language- since "contains" is open. However, the claim is indefinite because this is in conflict with applicant's arguments on page The GenBank record teaches an nucleic acid molecule comprising partial 16S rRNA sequence from *Mycobacterium cookii*. Regarding claim 16, the record is considered to teach a kit "containing" an oligonucleotide consisting of each of SEQ ID NO: 21-24. The use of the broad transitional phrase "containing" leaves the claim open so that the kit simply must "contain" the recited sequences. The molecule taught in the GenBank record contains each of SEQ ID NO: 21-24. Namely, SEQ ID NO: 21 is identical to nucleotides 58-82, SEQ ID NO: 22 is identical to nucleotides 59-82, SEQ ID NO: 23 is identical to nucleotides 62-83, and SEQ ID NO: 24 is identical to nucleotides 65-83 of the sequence given in the GenBank record. Thus the record teaches the kit claimed in claim 16.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister et al. (US 5908744), in view of GenBank X53896, GI: 44201, published 04 September 1991, and further in view of Buck et al. (BioTechniques, 27:528-536, September 1999).

McAllister et al. teach compositions and kits for synthesizing multiple copies of target nucleic acid which use a promoter-primer to initiate DNA and RNA synthesis, and that such methods preferably reduce non-specific product formation (See Abstract, for example, and Col. 4). McAllister et al. teach that preferred promoters include the T7 bacteriophage promoter (Col. 11, lines 5-10). McAllister et al. exemplify the use of such primers for the detection of Mycobacterium (Col. 13-15).

McAllister et al. do not teach oligonucleotides that comprise an oligonucleotide in a size range of about 19 to 25 bases containing 18 contiguous bases of SEQ ID NO: 24, or any of the additional nucleic acids required in the instant claims.

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The GenBank record teaches an nucleic acid molecule comprising partial 16S rRNA sequence from *Mycobacterium cookii*. Regarding claim 16, the record teaches an oligonucleotide having each of SEQ ID NO: 21-24. Namely, SEQ ID NO: 21 is identical to nucleotides 58-82, SEQ ID NO: 22 is identical to nucleotides 59-82, SEQ ID NO: 23 is identical to nucleotides 62-83, and SEQ ID NO: 24 is identical to nucleotides 65-83 of the sequence given in the GenBank record. Additionally the record provides nucleotides 5' to the portion which comprises SEQ ID NO: 24.

Regarding claims 14, the sequence taught in the GenBank record contains many fragments of SEQ ID NO: 11, each of which are oligonucleotides "of" SEQ ID NO: 11. The sequence taught in the GenBank record also comprises the complement of instant SEQ ID NO: 11 at nucleotides 341-367.

The sequences set forth in claims 15, 17, 18, 19, and 20 have been addressed.

Further, Buck expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely

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high quality (page 535, column 2).” Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

Thus, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have selected oligonucleotides from within the GenBank sequence useful for the amplification of *M. cookii* sequences. The selection of any oligonucleotide from within this sequence would have been expected to function equivalently with regard to the ability to *M. cookii* 16S sequences. One would have been motivated to provide primers that comprised any of the fragments of the GenBank record in order to provide a means for the amplification and detection of this *Mycobacteria* species. Further, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified any of the primers selected to have included a primer that is modified to include a 5' promoter sequence, particularly a T7 promoter sequence. The ordinary practitioner would have been motivated to make such compositions in order to carry out methods such as those taught by McAllister et al. and thereby to exploit the advantages of such methods, since McAllister et al. specifically teach that such methods reduce side reactions, and improve amplification (Col. 10, lines 39-58).

#### **Response to Remarks**

Applicant states that in view of the amendments to claim 16, it is clear that the claimed kit is distinguished from the teaching of the GenBank record. However, this is not persuasive in

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light of the open nature of the claim language as discussed in the newly set forth rejection which addresses the amended claim. However, to address such an interpretation of the amended claim, it is noted that this claim is also rejected under the 103 in this office action.

Applicant traverses the 103, arguing that Buck et al. do not demonstrate the equivalence of primers. Applicant points out that Buck et al. used a target sequence that had previously been shown to lack obstacles for sequence extension. This is not a flaw in Buck's showing but instead it would be expected that if one wanted to test the function of primers relative to one another one would begin with a target that was not problematic for amplification in order to remove on potential experimental design problem. The selection of target sequences that do not contain problematic areas was a routine practice in the technology area at the time the invention was made, as evidenced by Buck et al. Further, applicant points out that the primers used in Buck et al. were selected by "specialized laboratories" that provide sequencing services. Again, it seems natural and appropriate that Buck would look to those of ordinary skill in the relevant art to design primers. In this case, the level of "ordinary skill" is quite high. In the area of primer design one of ordinary skill in the art is one who specializes in designing primers. Applicant points out that the primers were tested under tightly controlled experimental conditions. Again, this is within the level of ordinary skill in the art- in order to effectively compare different primers, controlled experimental conditions would be required. And finally, applicant points out that Buck et al. trimmed the raw data prior to sequence analysis. There is no evidence on the record that this is an unusual analysis practice, despite applicant's suggestion. Arguments of counsel are not found to be persuasive in the absence of a factual showing. MPEP 716.01(c) makes clear that



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"The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant."

Applicant's position that all primers to the known M. xenopi sequence given in GenBank X53896 would not all function as equivalents would be better received in view of an evidentiary showing which demonstrates this assertion relative to the claimed products. The rejection is maintained.

### *Conclusion*

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.


The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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Juliet C. Switzer  
Primary Examiner  
Art Unit 1634

January 8, 2007